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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,671	11/26/2003	Robert H. Cichewicz	MSU 4.1-673	8778
21036	7590	09/09/2004	EXAMINER	
MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,671

Applicant(s)

CICHEWICZ ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 contain the phrase “**exposing** the helminth” to an active agent. The use of the term “exposing” is indefinite, as it is unclear as to what level the helminth and the active agent must be combined, as exposing does not require that actual contact is indeed made between the active agent and the helminth made. Clarity is respectfully requested.

Claims 2 and 3 contain the term of “**substituted**...”. In the absence of the identity of moieties which are intended to effectuate substitution, thus modifying the instantly claimed chemical core, the identity of the substituted final product would be difficult to ascertain. In the absence of said “substituted (modifying)” moieties, the claims containing the term “substituted” in all occurrences where not further defined, are not described sufficiently to distinctly point out that which applicant intends as the invention.

Claims 2 and 3 additionally provide the limitation of “R is a group containing 1 to 12 carbons selected from the group consisting of methyl, ... hydroxy, hydroxymethyl...”. It is unclear how a hydroxy group can be considered to contain 1 to 12 carbon atoms, as a hydroxy group does not contain any carbons.

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All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

Claim Rejections - 35 USC § 102

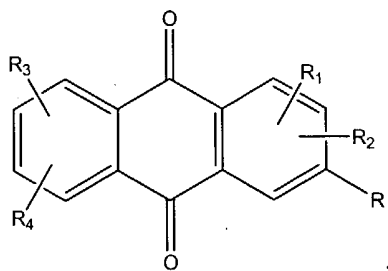
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Spainhour et al. ("Medical Attributes of *Polygonum cuspidatum* – Japanese knotweed", Wilkes University, July 1997, from the website: <http://wilkes1.wilkes.edu/~kklemow/Polygonum.html>).

Claim 1 is drawn to a method of inhibiting a parasitic helminth comprising exposing the helminth to an inhibitory amount of an anthraquinone. Claim 2 provides that the anthraquinone has the following structure:

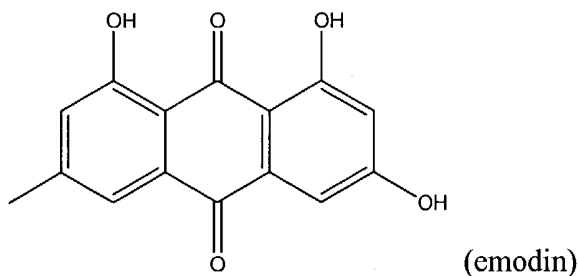


wherein R₁, R₂, R₃, and R₄ are each optionally H, OH, or methyl; and R is optionally OH.

Claim 6 provides the method is *in vitro* and claim 7 provides the method is *in vivo*.

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Spainhour et al. disclose that *P. cuspidatum* produces a compound known as emodin, which is an anthraquinone represented by the structure below (as evidenced by the ChemFinder.com document attached), and which has several effects, such as inhibiting the motor activity of a parasitic *Schistosoma* species (page 2, first full paragraph). *Schistosoma* are known in the art to be parasitic helminths.



The disclosure of emodin inhibiting the motor activity of a *Schistosoma* species by Spainhour et al. anticipates claims 1, 2, 6, and 7 of the instant application as the structure of claims 1 and 2 includes the compound emodin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spainhour et al. ("Medical Attributes of *Polygonum cuspidatum* – Japanese knotweed", Wilkes University, July 1997, from the website: <http://wilkes1.wilkes.edu/~kklemow/Polygonum.html>).

Claim 1 is drawn to the method of inhibiting a parasitic helminth by exposing said organism to an anthraquinone as set forth supra. Claim 2 sets forth the structure of the anthraquinone as set forth supra. Claim 3 defines R₁, R₂, and R₃ as OH and R₄ as H. Claim 4 provides that the compound is 1,2,8-trihydroxy-3-methyl anthraquinone. Claim 5 provides that the compound is 1,2,8-trihydroxy-3-hydroxymethyl anthraquinone. Claims 6 and 7 provide the inhibition is *in vitro* or *in vivo* respectively.

Spainhour et al. teach the inhibition of motor activity of *Schistosoma* species by administration of the anthraquinone as set forth supra. *Schistosoma* is known in the art to be a parasitic helminth. It is noted that the compound has the same core structure, and has the same substituents as claims 3-4 of the instant application, however, the substituents are located in

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various positions. However, obviousness based on similarity of structure and function entails motivation to make the claimed compounds in expectation that compounds similar in structure will have similar properties, and thus function similarly. It has been held that wherein a prior art compound essentially brackets the compounds claimed and are well known pesticides, for example, one of ordinary skill in the art would be motivated to make the various compounds in searching for new compounds. See *In re Payne*, 606 F.2d 303, 203 USPQ 245, 254-55 (CCPA 1979). In the instant case, anthraquinones which are overlapping in structure with the genus claim, and are structurally similar to the dependent claims, are known in the art to be effective in inhibiting the motor activity of *Schistosoma* species, thus one of ordinary skill in the art would expect the structurally related compounds to act in the same manner. Moreover, compounds which differ only in the placement of substituents in a ring system are not patentable absent unexpected results. See *In re Jones*, 162 F.2d 638, 74 USPQ 152 (CCPA 1947). Moreover, a showing must be commensurate with the scope of the claims. See *In re Kollman*, 102 USPQ 193 (CCPA 1979).

Conclusion

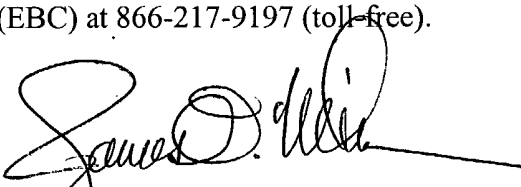
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
September 3, 2004



James O. Wilson
Supervisory Patent Examiner
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